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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/607,142 | 06/27/2003 | David Hung | 005284.00196 | 5158 |
| 38732 | 7590 | 03/28/2005 | | EXAMINER |
| CYTYC CORPORATION 250 CAMPUS DRIVE MARLBOROUGH, MA 01752 | | | KENNEDY, SHARON E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|----------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/607,142 | HUNG ET AL. | |
| | Examiner Sharon Kennedy | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 March 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06/26/2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiments of claims 27 and 35 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The claim states that the "outlet is configured, upon removal of a respective one of said probes, for closure to fluid flow." All applicant shows is a cover 47 to be applied to the open end of the manifold. However, the claim implies an automatic process. Although a valve is discussed in [0025], it is not shown or described. Accordingly, the claims must be cancelled or re-written.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 18-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 has been amended to require simultaneously collecting fluid samples from the at least two ductal networks. Applicant relies on page 2, lines 7-17 of the specification for support, but the examiner cannot find support in these lines. The specification only discloses the simultaneous infusion of the device, and this is easily accomplished using the manifold 30 of applicant's invention. However, collecting the ductal samples is performed via each duct and each syringe. Not only is there no disclosure of simultaneous collection, but also it seems difficult to accomplish unless there were an operator for each syringe. Applicant states the breast contains 9-12 ducts. A simultaneous collection would require 9-12 people.

If applicant is relying on the recited applications that are incorporated by reference, applicant should be aware that this is not permitted for essential material.

Claim Rejections - 35 USC § 102

Claims 18-24, 28-30, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeter et al., US 5,683,420. Note the instructions are not accorded patentable weight as they are printed matter. See *In re Ngai et al.*, CAFC 03-1524, May 13, 2004. Accordingly, the claims merely require an apparatus having the ductal access probes, which is shown by Jeter.

Regarding claim 18, this claim only requires at least two ductal access probes each having a lumen and being configured for introduction into the ductal network. Jeter clearly shows this.

Regarding claims 19 and 20, see Jeter figure 3. The claimed manifold has already been pointed out as being anticipated by Jeter feed septum 14.

Regarding claims 21 and 24, see figure 7. The access probes are 13c and 13c. The plurality of receptacles (or plurality of collection tubes) are anticipated by fluid receptacles S.

Regarding claims 22, 23, 36 and 37, these claims recite only instructions in the kit. This is printed matter and is not accorded patentable weight.

Regarding claim 28, see Jeter figure 3. Jeter feed septum 14 anticipates the manifold; container 12 anticipates the collection tube. The instructions, as stated above, are not accorded patentable weight.

Regarding claims 29 and 30, the fluid control device is anticipated by clamp 9.

Claims 25 and 31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jeter '420.

Regarding claims 25 and 31, applicant's comments have been convincing. See especially figure 7 of Jeter. Jeter discloses the two ductal access probes (13c and 13c coupled with 8 and 8), each having a lumen, the plurality of collection tubes (reservoir bags S and S), but Jeter does not disclose the fluid control device capable of controlling fluid flow in each respective ductal access probe. However, see Jeter clamp 9 shown in the other figures. The examiner takes the position that clamps in infusion tubes are so old they are not always shown on every line. Accordingly, it is inherent that each line 8 includes a clamp. In the alternative, it would be obvious to one of ordinary skill in the art to add clamps to lines 8 to control fluid flow. If a clamp were added to each of lines 8 in figure 7, then the claimed "fluid control device capable of controlling fluid flow in the lumen of each respective ductal access probe" is met.

Claims 25 and 31 also require that each collection tube comprise a fluid control device. Note that Jeter states that syringe 16 (figure 4) "is shown for inclusion of possible reservoirs." See column 5, lines 6-7. The examiner takes the position that Jeter discloses that a syringe 16 may be substituted to each of the reservoir bags S. Thus the syringe pistons/plungers control fluid flow in each claimed collection tube. In the alternative, it would be obvious to use the syringe of figure 4 instead of the fluid reservoir bags of figure 7 because Jeter states that this substitution is desirable. In addition, see column 2, lines 50+. The reservoir pressure can be altered by raising or

lowering the reservoir, or by applying air pressure to the reservoir. This also meets the claimed "fluid control device."

Claim Rejections - 35 USC § 103

Claims 26, 27, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeter. Jeter discloses all of the claimed embodiments (see especially figure 3) but is silent on the connectability of the device. In addition, claims 27 and 35 recite that removing a ductal probe closes fluid flow therefrom. Regarding the connectability of the device, it is well settled that making a device integral or separable is *prima facie* obvious in the lack of a showing of criticality. See MPEP 2144.04 V. C., entitled, "Making Separable." Applicant's specification has not set forth any unusual effect resulting from making the parts separable; accordingly, these claims are rejected. Regarding claims 27 and 35, see the deficiencies set forth above with respect to the drawings. The examiner is interpreting these claims to mean a removable cover 47 as shown by applicant in figure 2A. Again, it is an obvious design choice to make a device separable or integral. It is well known that the breast contains multiple ducts and each patient may have a different number. Jeter seems to acknowledge this by describing a watch glass 18 having a plurality of holes that each may be used for catheter insertion or individually plugged with rubber plugs or tabs.

Double Patenting

Claims 18-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 51 of copending Application No. 09/907,931.

Claims 18-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-29 (withdrawn from prosecution) of copending Application No. 10/858,086.

Claims 18-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-42 of U.S. Patent No. 6,398,765.

Claims 18-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,629,936.

Regarding the double patenting rejections, see the comments set forth in the previous rejections.

It is becoming common to delay filing the terminal disclaimer(s) until all the claims are indicated as allowable. However, this places a burden on the examiner and the USPTO to conduct additional paper processing, docketing, and examination. Accordingly, applicant must file the terminal disclaimer(s) in response to this office action or supply substantive arguments against the double patenting rejection(s).

Response to Arguments

Applicant's arguments filed February 4, 2005 have been considered but they are not fully persuasive. Note that the devices such as valves, pumps, syringes, etc., which are recited in the instructions, are ignored. For example, the only part of the body of claim 1 which has patentable significance is "an apparatus comprising at least two ductal access probes each having a lumen and being configured for introduction into a respective one of the ductal networks for the breast."

Allowable Subject Matter

Claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if terminal disclaimers were filed as suggested above.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.


Sharon Kennedy
Primary Examiner
Art Unit 3762

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